Shedding some light on FDA’s review of sunscreen ingredients and the Sunscreen Innovation Act

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With recent record snowfalls in many parts of the country, the use of sunscreens may not have been on many people’s minds. But here at FDA, sunscreens have been a front-and-center issue.

On November 26, 2014, Congress enacted the Sunscreen Innovation Act (SIA) that provides a new process for the review of safety and effectiveness of nonprescription sunscreen active ingredients. Among other things, the SIA creates timelines for FDA review.

Before the law was enacted we followed the regulatory process known as the Time and Extent Applications process, or TEA process for sunscreen active ingredients. This regulatory process provides, among other things, a mechanism for sponsors to request that FDA evaluate active ingredients that are used in over-the-counter (OTC) drug products, particularly those marketed in other countries. The TEA process can be summarized in two basic steps. Step 1 is FDA’s determination of eligibility, made upon a showing that the
ingredient has been marketed over-the-counter in one or more countries for a material time and extent. Step 2 is FDA’s evaluation of the data to determine whether the ingredient is generally recognized as safe and effective (GRASE) for its intended use in an OTC drug product as described in the relevant regulation. If, after review of the data, FDA ultimately finds the ingredient to be GRASE for its intended OTC use, the ingredient may enter the U.S. marketplace. There were eight TEAs for sunscreen ingredients submitted to FDA before the SIA went into effect.

On January 7, we met the first requirement of the SIA. In doing so, we announced our tentative determinations that six of these ingredients are not GRASE for use in sunscreens because we need more data from the manufacturers to help establish the safety and effectiveness of these products.

Today, we completed another requirement by taking initial action on the last two pending ingredients, ecamsule and enzacamene. We tentatively determined, as we had with the other six ingredients, that we need more data to decide if these ingredients are, in fact, GRASE for use in OTC sunscreen products. Information about the SIA and our recent actions under the law are available on our new web page for this topic.

At this time there is not enough generally available data to determine whether any of the ingredients under review meet FDA’s safety and effectiveness standards.

We know our careful actions to seek more information may be disappointing to some who would like to see additional sunscreen products on the market immediately, but I’d like to take this opportunity to clarify some misconceptions about the SIA and the process for making sunscreen ingredients available for use in OTC products marketed without individual premarket review in the U.S.:

- The law does not change FDA’s standard for general recognition of safety and effectiveness. The SIA requires strict deadlines for FDA to take action on these ingredients, but it does not relax the FDA’s scientific standards for evaluating the ingredient’s safety and effectiveness, or our need for adequate data on which to base such determinations.
- The law does not provide FDA with additional resources. Recognizing the public health importance of sunscreen use, the FDA is proceeding as quickly as practicable to meet the requirements of the legislation. To assist in this process and to reduce the negative impact on other work, FDA is requesting funds for implementation of the SIA as part of the President’s fiscal year (FY) 2016 budget.
- The SIA does not guarantee that products with additional sunscreen ingredients will be on the market in a specified timeframe. Because additional data are needed for each of the eight sunscreen ingredients, timelines for FDA actions are triggered by industry’s submission of required data.
- There is apparent confusion as to why ingredients that have been on the market for
years in other countries cannot be used in the U.S. without further review by FDA. While information on marketing history in other countries is helpful, what we can learn from it is limited. For example, such information doesn’t tell us anything about the long-term effects from use of the ingredient or how much is absorbed. Because of the widespread daily use of sunscreen products by a broad population, including babies and pregnant women, FDA has proposed data requirements that will allow us to determine that sunscreen ingredients are generally recognized as safe and effective. These data requirements were unanimously supported by a panel of scientific experts at a recent public Advisory Committee meeting on sunscreens.

We cannot achieve success in bringing additional sunscreens to market on our own. FDA is committed to doing our best to meet the new statutory deadlines, and we will be transparent in our process and progress. Successful implementation of the SIA will require a cooperative effort with industry and other stakeholders. We look forward to continuing this important work.

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